



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1842]

Compliance Policy Guide on Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of Escherichia coli

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a Compliance Policy Guide (CPG) relating to fresh and frozen crabmeat adulteration with filth involving the presence of Escherichia coli (E. coli). The CPG updates the previously issued CPG on this topic. The CPG provides guidance for FDA staff on the level of E. coli in crabmeat at which we may consider the crabmeat to be adulterated with filth.

DATES: Submit electronic or written comments on FDA's CPGs at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social

Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-1842 for "Compliance Policy Guide on Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of Escherichia coli." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to Office of Policy and Risk Management, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Mary E. Losikoff, Center for Food Safety and Applied Nutrition (HFC-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2300.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of revised CPG Sec. 540.275 Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of Escherichia coli. The CPG updates the previously issued CPG Sec. 540.275 Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of Escherichia coli. We are issuing this CPG consistent with our good guidance practices regulation (21 CFR 10.115). The CPG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

The CPG provides guidance for FDA staff on the level of E. coli in fresh or frozen crabmeat (i.e., 3.6 Most Probable Number per gram (MPN/g) of E. coli) at which FDA may consider the crabmeat to be adulterated with filth under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4)). We revised the CPG for clarity and to update the format. Revisions generally include the addition of sections on Background and Policy, updates

to the sections on Regulatory Action Guidance and Specimen Charges, and FDA office names. The CPG provides criteria that the FDA District Offices may use to determine whether to recommend an enforcement action. Consistent with our standard business process, the CPG provides guidance to the FDA field offices for submitting an enforcement action recommendation to FDA's Center for Food Safety and Applied Nutrition (CFSAN) for case review. The CPG also provides direct reference authority to the FDA field offices in certain situations. Rather than submitting the recommendation to CFSAN, direct reference authority allows the FDA field offices to submit the recommendation directly to the appropriate office in FDA's Office of Regulatory Affairs, thus streamlining the Agency's internal case review process. Specifically, in the section on Regulatory Action Guidance, we clarify that FDA's District Offices have direct reference authority for both domestic seizure and import refusal based on the criteria described in the CPG. We also clarify the specific types of legal action to which the criteria for recommendations apply. In addition, we provide specimen charges relating to domestic seizure and import refusal. The CPG also contains information that may be useful to the regulated industry and to the public.

In the Federal Register of December 16, 2014 (79 FR 74729), we made available draft CPG Sec. 540.275 "Crabmeat--Fresh and Frozen--Adulteration with Filth, Involving the Presence of Escherichia coli." We gave interested parties an opportunity to submit comments on the draft CPG by February 17, 2015, for us to consider before beginning work on the final version of the CPG. We received no comments on the draft CPG. We are issuing the CPG with no changes other than for clarity and to update the format. The CPG announced in this notice finalizes the draft CPG dated December 2014.

II. Electronic Access

Persons with access to the Internet may obtain the CPG at either <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the CPG.

Dated: April 25, 2016.

Katherine Bent,

Assistant Commissioner for Compliance Policy.

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